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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,773	06/20/2003	Martin Grunwald	100727-50/Heraeus 402-KGB	6455

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EXAMINER	
MCKANE, ELIZABETH L	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,773	GRUNWALD ET AL.	
	Examiner	Art Unit	
	ELIZABETH L. MCKANE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 August 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 9-11, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wanek et al. (US 6,121,362) in view of Quintero et al. (US 6,547,467).

Wanek et al. teaches the known use of polysiloxane-based dental impression materials in a two-part system, wherein the multiple components of the composition are stored within a double-chambered cartridge until use in order to prevent premature crosslinking thereof. See col.2, line 64 to col.3, line 22. Wanek et al. does not disclose radiation sterilization of the separate components within the double-chambered cartridge.

Quintero et al. discloses that it was known in the art at the time of the invention to package two separate, unmixed components within a packaging device wherein the entire assembly is then sterilized with gamma radiation. Specifically, Quintero et al. evidences packaging a polymerizable and/or crosslinkable monomer and polymerization initiator or accelerator within distinct and separate parts of a packaging syringe. See col.4, lines 1-27; col.14, lines 38-45; col.15, lines 33-36. The syringe and its contents are then sterilized with gamma radiation. See col.17, lines 33-44; col.18, lines 1-8. Furthermore, Quintero et al. teaches that the final polymeric composition is to be used in medical applications.

It would have been obvious to one of ordinary skill in the art to sterilize the composition of Wanek et al. since Quintero et al. evidences that compositions intended for *in vivo* use must be sterilized. Moreover, it would have been obvious to radiation sterilize the components of Wanek et al. within the dual-chambered cartridge of Wanek et al., as Quintero et al. discloses that it was known in the art to achieve a sterile and non-polymerized product using radiation sterilization.

4. Claims 6, 7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wanek et al. and Quintero as applied to claim 1 above, and further in view of Cavezzan (US 4,741,966).

Wanek et al. discloses that an additional organosiloxane containing aromatic C_6-C_{12} substituents may be added to the composition in an amount of 0-40%. See col.6, lines 9-22. Wanek et al. does not specify that the aromatic C_6-C_{12} substituents are diphenyl- or phenyl methyl- siloxane units.

Cavezzan teaches that it was known in the art at the time of the invention to include either methylphenylsiloxane or diphenylsiloxane units in a two-part dental impression composition. See col.5, lines 54-56; col.4, lines 21-26 and lines 35-42. As these particular organosiloxane units are well-known in the art of dental impression materials, the use of such as the aromatic C_6-C_{12} organosiloxanes of Wanek et al. would have been obvious as providing predictable and expected results to one in the art.

5. Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wanek et al. and Quintero as applied to claim 1 above, and further in view of Larson et al. (US 5,540,876).

The combination of Wanek et al. with Quintero teaches use of gamma radiation for the sterilization of polymerizable materials but is silent with respect to a dose. Larson et al. discloses the use of gamma radiation for the sterilization of dental impression materials (col.1, lines 11-12; col.2, lines 61-67). A dosage less than 6 megarads (60 kGY) is necessary to avoid cross-linking of the material. See col.9, lines 16-17. Thus, it would have been obvious to employ a dose less than 60 kGy, optimized through routine experimentation, when using the gamma radiation of Quintero to sterilize the composition of Wanek et al..

6. Claims 1, 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oxman et al. (US 5,718,577) in view of Quintero.

Oxman et al. teaches the known use of polymerizable alginate two-part compositions in use for dental impressions. See col.1, lines 25-35, lines 51-58. The

two-parts are maintained separately until use. Oxman et al. does not disclose radiation sterilization of the separate components within a packaging unit.

Quintero et al. discloses that it was known in the art at the time of the invention to package two separate, unmixed components within a packaging device wherein the entire assembly is then sterilized with gamma radiation. Specifically, Quintero et al. evidences packaging a polymerizable and/or crosslinkable monomer and polymerization initiator or accelerator within distinct and separate parts of a packaging syringe. See col.4, lines 1-27; col.14, lines 38-45; col.15, lines 33-36. The syringe and its contents are then sterilized with gamma radiation. See col.17, lines 33-44; col.18, lines 1-8. Furthermore, Quintero et al. teaches that the final polymeric composition is to be used in medical applications.

It would have been obvious to one of ordinary skill in the art to sterilize the composition of Oxman et al. since Quintero et al. evidences that compositions intended for *in vivo* use must be sterilized. Moreover, it would have been obvious to radiation sterilize the components of Oxman et al. within a packaging unit, as Quintero et al. discloses that it was known in the art to achieve a sterile and non-polymerized product using radiation sterilization within a primary packaging unit.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is

(571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
15 September 2008